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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,640	12/08/2000	Anthony J. McHugh	10322/8	2399

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/733,640	Applicant(s) MCHUGH ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on th cover sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,17,18,34 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,17,18,34 and 38* is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

After-Final Amendment B received on December 3, 3003 has been entered. Claims 1-8, 17-18, 34, 38, and 48-57 are included in the prosecution of this application. Claims 20-33, 35-37, and 40-47 are cancelled.

Response to Amendment

Upon reconsideration, new prior art, and applicant's arguments, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathiowitz et al (5,912,017).

Mathiowitz et al teach multiwall polymeric microspheres. The microsphere contains two polymers (polystyrene and polyanhydride), a solvent, and a drug (examples).

*Note without specific parameters, the term "crystallizable" polymer is an intended use phrase and the polymer does not have to be crystallized, therefore it is the examiner's position that there is not patentable difference between the two polymers. Further, dependent claims, recite the same polymer, i.e. polyester, without specific parameters, which make them distinguishable from each other.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 34, 38, 49, 51-53, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Shukla (6,432,438).

Shukla teaches a biodegradable vehicle containing a drug, solvent, two different polymers (PLGA and PCL), and polyol (PEG), that is injected into an organism (examples, esp. 29). The method of mixing the polymer, solvent, and drug are taught in examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 6, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathiowitz et al (5,912,017).

Assuming the examiner has interpreted the claims improperly, Mathiowitz wt al would render instant claims obvious since instant specification page 5 defines crystallizable polymers as polylactic acids, polyglycolic acids, polyanhydrides, etc. and amorphous polymers as polyurethanes, polyamides, etc. Mathiowitz et al teach biodegradable polymers such as polyanhydrides, polylactic acid, polyglycolic acid, etc. and the second polymer (non-degradable) as polyurethane, polystyrene, and polyamides on column 3, lines 45-60. One would be motivated to look to Mathiowitz since the reference provides a general guidance in making multi-layered compositions containing instant polymers and polymer blends.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathiowitz et al (5,912,017).

As set forth above, Mathiowitz et al teach multiwall polymeric microspheres. The microsphere contains two polymers (polystyrene and polyanhydride), a solvent, and a drug (examples). The reference teaches the use of emulsifiers (col. 4, line 54).

The reference does not exemplify the use of an emulsifying agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an emulsifying agent in the composition since Mathiowitz suggests the use of such agents.

Claims 2-3 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathiowitz et al (5,912,017) in view of Brodbeck et al (6,130,200).

As set forth above, Mathiowitz et al teach multiwall polymeric microspheres. The microsphere contains two polymers (polystyrene and polyanhydride), a solvent, and a drug (examples).

The reference does not teach instant solvent/solvent mixtures or polycaprolactone.

Brodbeck et al disclose a gel composition containing a biocompatible polymer, ethyl or benzyl benzoate, a biocompatible component solvent, a bioactive agent, and an emulsifier. (Note Examples, Tables 1-2) Brodbeck teaches biodegradable polymers include polylactides, polyglycolides, polyanhydrides, and polycaprolactone (col. 10, lines 65-68). Brodbeck teach a solvent having a solubility in water of less than 7% allows for suitable burst control and sustained release of the beneficial agent col. 8, lines 48-60). Brodbeck teaches for the preferred polymer PLGA, benzoic acid solvents are preferred (col. 14, lines 1-6). Brodbeck also teaches an injectable gel composition (col. 18, lines 56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mathiowitz and Brodbeck since both teach controlled polymer delivery systems. One would be motivated to use instant solvent since Brodbeck states that instant solvent has certain properties that allow controlled release of the active agent. Further motivation being that both reference teach similar polymers, therefore one of ordinary skill could reasonably expect similar results.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shukla (6,432,438).

As set forth above, Shukla teaches a biodegradable vehicle containing a drug, solvent, two different polymers (PLGA and PCL) that is injected into an organism (examples, esp. 29). The method of mixing the polymer, solvent, and drug are taught in examples. Among the polymers taught, polylactides are taught as suitable for invention (col. 1, lines 27-40).

Shukla does not exemplify instant polylactide polymer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use polylactide in the composition. One would be motivated to do so with the expectation of similar results since Shukla teaches the suitability of polylactides in the composition.

Claims 48, 50, 54, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shukla (6,432,438) in view of Brodbeck et al (6,130,200).

Shukla teaches a biodegradable vehicle containing a drug, solvent, two different polymers (PLGA and PCL) that is injected into an organism (examples, esp. 29). The method of mixing the polymer, solvent, and drug are taught in examples.

Shukla does not teach instant solvent or emulsifying agent.

Brodbeck et al disclose a gel composition containing a biocompatible polymer, ethyl or benzyl benzoate, a biocompatible component solvent, a bioactive agent, and an emulsifier. (Note Examples, Tables 1-2) Brodbeck teaches biodegradable polymers include polylactides, polyglycolides, polyanhydrides, and polycaprolactone (col. 10, lines

65-68). Brodbeck teach a solvent having a solubility in water of less than 7% allows for suitable burst control and sustained release of the beneficial agent col. 8, lines 48-60). Brodbeck teaches for the preferred polymer PLGA, benzoic acid solvents are preferred (col. 14, lines 1-6). Emulsifying agents are taught for an injectable depot gel composition (col. 18, lines 56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Shukla and Brodbeck since both teach controlled polymer delivery systems. One would be motivated to use instant solvent since Brodbeck states that instant solvent has certain properties that allow controlled release of the active agent. Further motivation being that both reference teach similar polymers and injectable gel compositions; therefore one of ordinary skill could reasonably expect similar results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG
LDT
December 6, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER